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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/658,969	09/11/2000	Winfried Edelmann	AHN-001DV2	5790

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/04/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/658,969

Applicant(s)

EDELMANN ET AL.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17 and 22-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 15-17 and 22-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All' b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

This is a new ground of restriction requirement based on Applicants' preliminary amendment filed 11 September 2000 (paper No. 7), in which Applicants state cancellation of Claims 1-14 and 18-21 and amendment of Claims 15 and 16. Thus, Claim Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 24, drawn to a polynucleotide, classified in class 536, subclass 23.1.
- II. Claim 25, drawn to small molecules that are of non-organic and non-peptide and characteristics, classified in class 260.
- III. Claims 26, drawn to antibody specifically recognizes and binds MSH5, classified in class 530, subclass 387.1.
- IV. Claim 27, drawn to polypeptide, classified in class 435, subclass 350, and class 514, subclass 2.
- V. Claim 28, drawn to peptidomimetic substance which is not a polypeptide or peptide, classified in class 564, subclass 152, class 514, subclass 23 and 54.
- VI. Claim 29, drawn to a substance having an effect on substrate for MSH5, substance can be nucleotide, classified in class 435, subclass 89⁺, or other organic compound, classified in class 552, subclass 500⁺.

The inventions are distinct, each from the other because of the following reasons:

Invention I, II, III, IV, V and VI are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention I is drawn to polynucleotide whole Invention IV is drawn to a peptide or polypeptide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to

exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to an expression vector in which the polynucleotides directs synthesis of gene products, where directed to polynucleotide molecules being transferred into an cultured cell, which process would have been searched in class 435 subclass 69.1.

Invention I (polynucleotide) and Invention III (Antibody) are patentably distinct from each other because of the materially different structures of the compounds claimed. The Invention I is drawn to polynucleotide, while Invention III is drawn to immuoglobulin, a type of polypeptide. The biopolymers that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to an expression vector in which the polynucleotides directs synthesis of gene products, where directed to polynucleotide molecules being transferred into an cultured cell, which process would have been searched in class 435 subclass 69.1. Invention III is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Invention I (polynucleotide) is patentably distinct from Invention II (small molecules), Invention V (peptidomimetic substance) and Invention VI (modulator of MSH5 substarte), because of the materially different structures of the compounds claimed as the same reasons

Art Unit: 1653

given in the foregoing statement.

Invention II and VI are different products. Small molecule that are not peptide, nucleic acid and organic compound, and a peptidomimetic substance differ with respect to their structures (non-polymer versus polymer) and physicochemical properties (small molecule is not necessary act as peptidomimetic compound but peptidomimetic substance mimics function of polypeptide); therefore each product is patently distinct.

Invention II and Invention VI are distinct products, one is a small molecule binding to MSH5 protein (Invention I), e.g. ATP, and another a substance acting as a modulator for MSH5 substrate e.g. metal ions. For the same reason, Invention II is different from Invention V, for the instance, ATP (capable of binding to MSH5 protein, Invention II) is not peptidomimetic substance (Invention V).

Invention II, Invention III and Invention IV are distinct products because the small molecule (Invention II) is both structurally and functionally different from bio-macromolecules, antibody (Invention II) and polypeptide (Invention IV).

Invention IV (polypeptides) and Invention III (antibody) are distinct from each other because of the materially different structures of the compounds claimed. The Invention I is drawn to a peptide or polypeptide, while Invention II is drawn to immunoglobulin. The bio-macromolecules that are the subject of each group are independent and/or patently distinct from each other because each macromolecule is structurally distinct. The macromolecule of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate use and manufacture.

Invention III is also patently distinct from Invention V (peptidomimetic substance) and

Art Unit: 1653

Invention VI (a modulator for MSH5 substance) because antibody (Invention III) structurally and functionally different from non-immunoglobulin molecules, hereof, peptidomimetic substance and different from a modulator for MSH5 substance, e.g. metal ion.

For the same reason stated above, Invention V is patentably distinct from Invention IV since peptidomimetic substance (Invention V) is structurally different from a substance that is an effector of MSH5 substrate, metal ion, for example.

Irrespective of whichever groups (I-V) applicants elect, Claims 15-17, 22, 23, 30 and 31 will be examined to the extent that the above claims read on the elected group and compound administered therein.

Because reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

Art Unit: 1653

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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SWL

June 3, 2002


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600